



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/049,366 | 05/10/2002 | Mic Takahashi | 967-026 | 1103 |

7590 08/23/2004
Wall Marjama & Bilinski
Suite 400
101 South Salina Street
Syracuse, NY 13202

EXAMINER

LUM, LEON YUN BON

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 1641 | |

DATE MAILED: 08/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|---|--|
| Office Action Summary | Application No. 10/049,366 | Applicant(s) TAKAHASHI ET AL. | |
| | Examiner Leon Y Lum | Art Unit 1641 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 February 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 May 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Priority

1. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Japan on 01 June 2000. It is noted, however, that applicant has not filed a certified copy of the 2000-164990 application as required by 35 U.S.C. 119(b).

Information Disclosure Statement

2. The information disclosure statements filed 13 May 2002 and 11 February 2003 fail to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of the 11-505327 and 1 140 462 patents listed, which are not in the English language. They have been placed in the application file, but the information referred to therein have not been considered.

In addition, there is no concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of the 01262470A and 06094718A patents, which are not in the English language, except for the abstract. Therefore, they have been placed in the application file, but only the abstract has been considered.

Claim Objections

3. Claims 2-3 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 2-3 recite "a liquid specimen to be added" (line 2 of the claims), which is a method step that does not further limit the device of claim 1.

4. Claims 17-19 and 28-30 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The instant claims recite types of processes by which the "carrier" is "dried". However, the processes of claims 17-19 and 28-30 do not further limit the parent claims of 12 and 23, respectively, since it doesn't matter how the carrier is dried in order to perform the method steps of the parent claims.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. In claim 1, line 3, and claims 12 and 23, line 4, the phrase "utilizing chromatography" is vague and indefinite. The specification does not provide a definition for the phrase and it is unclear how chromatography is utilized in the biosensor.

8. In claim 1, lines 4-6; claim 12, lines 6-7; and claim 23, lines 7-9, the phrase "at least part of the reagent holding part, or at least part of a chromatographically developed part" is vague and indefinite. It is unclear whether the cell shrinkage reagent (line 4) is being claimed is carried on "at least part of the reagent holding part" or "at least part of a chromatographically developed part".

9. In claim 1, line 6; claim 12, line 7; and claim 23, lines 8-9, the term "chromatographically developed part" is vague and indefinite. The specification does not provide a definition for the term and it is unclear as to what the term means and which part of the biosensor is considered "chromatographically developed". The

Art Unit: 1641

Examiner interprets the term "chromatographically developed part" as any part of a biosensor that is able to perform any function of chromatography.

10. In claim 23, lines 5-6, the phrase "cell components shrink or shrink while being chromatographically developed in a state where shrunk cell components are mixed" is vague and confusing. It is not clear what is being claimed and what the difference is between the first "shrink" step and the second. It is also not clear what "shrink while being chromatographically developed" means. The specification does not provide a definition for that part of the phrase and it is not clear what steps for "being chromatographically developed" are involved.

11. Claims 7-9, 17-19, and 28-30 recite the limitation "a carrier that carries the cell shrinkage reagent" in line 2 of the claims. There is insufficient antecedent basis for this limitation in the claim. The parent claims of 1, 12, and 23 do not recite a carrier and it is unclear from the instant claims where the carrier is placed within the biosensor device.

12. Claims 12 and 23 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: how the separation of cell components that are shrunk is related to a blood component analytical method. The preamble of the claim recites "a blood component analytical method", but the body of

Art Unit: 1641

the claim only recites the step of separating shrunk cell components. Where are the steps that connect separating shrunk cell components to analyzing a blood component?

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. Claims 1-4, 7-14, 19, 21-25, 30, and 32-34 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Killeen et al (US 5,166,051).

For claims 1-4 and 7-11, Killeen et al reference teaches a biosensor that is made of a single layer of a porous material, said biosensor having a reagent holding part and utilizing chromatography, wherein a cell shrinkage reagent is carried on at least part of a chromatographically developed part, which is upstream of the reagent holding part, wherein a liquid specimen to be added is whole blood (claim 2), and wherein a carrier carries the cell shrinkage reagent (claims 7-9), by disclosing a diagnostic test strip for the chemical or immunological assay of whole blood analytes that comprises a substrate, a porous detection zone membrane affixed to the substrate, and an overlay membrane affixed to the substrate and in overlying and continuous contact with the detection zone membrane (column 2, lines 54-67), wherein the overlay membrane

Art Unit: 1641

generally comprises a porous membrane of varying thickness containing a crenating agent which functions to deplete the volume of fluid within the red blood cell, wherein once the cell becomes crenated or has been shrunk, it is much less malleable and flexible and becomes rigid, and in turn, less able to penetrate into the pores of the detection zone membrane (column 5, lines 5-14 and 36-41).

For claims 12-14, 19, 21-25, 30, and 32-34 Killeen et al reference teaches a blood component analytical method in which a biosensor that is made of a single layer of a porous material, said biosensor having a reagent holding part and utilizing chromatography, is employed, wherein cell components shrink and the shrunk cell components are separated in an area of at least part of a chromatographically developed part that is upstream of the reagent holding part, on which a cell shrinkage reagent is carried, and wherein a blood specimen to be added is whole blood (claims 13 and 24), by disclosing a general method for using the diagnostic test strip of the invention comprising a support, a detection zone membrane, and an overlay membrane for the chemical or immunological assay of whole blood analytes comprises the steps of applying sample of whole blood to the overlay membrane and analyzing a signal generated from the detection zone membrane to determine the presence of any given analyte (column 8, lines 51-58), and wherein the porous detection zone membrane, overlay membrane, and crenating agent in the overlay membrane which functions to shrink red blood cells to make them less able to penetrate into the pores of the detection zone membrane have been disclosed above.

With regards to claim 3, Killeen et al reference also teaches a liquid specimen to be added is a solution including bacteria, by disclosing that virtually any analyte detectable using an immunological or chemical assay can be detected using the test strip system, including bacteria (column 6, lines 11-18).

With regards to claims 4, 14, and 25, Killeen et al reference also teaches that the cell shrinkage reagent is inorganic salt, by disclosing that the crenating agent may be any constituent or composition which effectively reduces the volume of water within the RBC flowing through the overlay membrane and particularly useful are inorganic and organic salts (column 5, lines 48-52).

With regards to claims 10, 21, and 32, Killeen et al reference also teaches that the biosensor is a one-step immunochromatographic test strip, by disclosing that the test strip of the invention can be employed in a variety of device formats and that a detection zone for the detection of analytes can be formed on a carrier strip to which a volume of blood can be applied for the purpose of determining the presence of the target analyte in the blood serum (column 7, lines 57-62), wherein the blood is whole blood (column 2, lines 59-61), and that the test system can be used in a preferred immunoassay wherein the test strip of the present invention comprises a matrix of three zones for a test fluid containing target analyte to flow through with the addition of further liquid solutions (column 8, lines 59-68 and column 9, lines 1-24).

With regards to claims 11, 22, and 33, Killeen et al reference also teaches that the biosensor is a dry analytical element, by disclosing that the dry test strips of the

invention can be manufactured by applying an overlaying adhesive on the support carrier (column 8, lines 40-42).

With regards to claims 19 and 30, Killeen et al reference also teaches that a carrier that carries the cell shrinkage reagent is dried by heat-drying, by disclosing that various overlay membranes were impregnated with a one molar NaCl solution and then dried at 75°C (column 11, lines 18-20).

With regards to claims 31 and 34, Killeen et al reference also teaches that the concentration of the cell shrinkage reagent is 0.1 ~ 5.0M or 0.05 ~ 5.0M, respectively, by disclosing that various overlay membranes were impregnated with one molar NaCl solution (column 11, lines 18-20) or treated with a 1 M NaCl (column 12, lines 4-5).

In claim 7, 17, and 28 the limitation "dried naturally or dried by air-drying" (lines 2-3) is considered a product-by process claim and therefore is not given any patentable weight and therefore only the structural limitation of "a carrier that carries the cell shrinkage reagent" (line 2) has been considered.

In claim 8, 18, and 29 the limitation "dried by freeze-drying" (lines 2-3) is considered a product-by process claim and therefore is not given any patentable weight and therefore only the structural limitation of "a carrier that carries the cell shrinkage reagent" (line 2) has been considered.

In claim 9, 19, and 30 the limitation "dried by heat-drying" (lines 2-3) is considered a product-by process claim and therefore is not given any patentable weight and therefore only the structural limitation of "a carrier that carries the cell shrinkage reagent" (line 2) has been considered.

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

17. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

18. Claims 5-6, 15-16, and 26-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Killen et al (US 5,166,051) in view of Fruitstone et al (US 4,259,207).

Killeen et al reference has been disclosed above, but fails to disclose that the cell shrinkage reagent is amino acid or saccharide.

Fruitstone et al reference teaches that solutes such as amino acids and sugars may be employed to control osmolality, in order for cells to become crenated if the osmolality of the solution is too high (column 3, lines 3-20).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device and method of Killeen et al, with solutes such as amino acids and sugars that may be employed to control osmolality, as taught by Fruitstone et al, in order for cells to become crenated if the osmolality of the solution is too high. One of ordinary skill in the art at the time of the invention would have reasonable expectation of success in using amino acid or sugar, as taught by Fruitstone et al, in the device and method of Killeen et al, since Killeen et al teach that the crenating agent may be any constituent or composition which effectively reduces the volume of water in blood cells, as disclosed above, and amino acids and sugars are examples of constituents that reduce the volume of water in blood cells.

19. Claims 6, 16, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Killen et al (US 5,166,051) in view of Cremins et al (US 4,978,624).

Killeen et al reference has been disclosed above, but fails to disclose that the cell shrinkage reagent is saccharide.

Cremins et al reference teaches a high solute concentration of a reagent solution with sugar content, in order to crenate blood cells (column 5, lines 3-10).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device and method of Killeen et al, with a high solute concentration of a reagent solution with sugar content, as taught by Cremins et al, in order to crenate blood cells. One of ordinary skill in the art at the time of the invention would have reasonable expectation of success in using glucose sugar, as taught by Cremins et al, in the device and method of Killeen et al, since Killeen et al teach that any crenating agent may be any constituent or composition which effectively reduces the volume of water in blood cells, as disclosed above, and glucose sugar is one example of a constituent that reduces the volume of water in blood cells.

20. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Killen et al (US 5,166,051) in view of Maimon et al (US 5,350,693).

Killeen et al reference has been disclosed above, but fails to disclose that the concentration of the cell shrinkage reagent is 0.05 ~ 0.3M.

Maimon et al reference teaches a hypertonic media with 0.3M NaCl in order for the hypertonic media to produce shrinking of cells (column 6, lines 35-36 and 45-47).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Killeen et al, with a hypertonic media with 0.3M NaCl,

Art Unit: 1641

as taught by Maimon et al, in order for the hypertonic media to produce shrinking of cells. One of ordinary skill in the art at the time of the invention would have reasonable expectation of success in using 0.3M NaCl, as taught by Maimon et al, in the device of Killeen et al, since Killeen et al teach that any crenating agent may be any constituent or composition which effectively reduces the volume of water in blood cells, as disclosed above, and NaCl at a concentration of 0.3M is an example of a constituent that reduces the volume of water in blood cells.

Conclusion

21. No claims are allowed.

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leon Y Lum whose telephone number is (571) 272-2878. The examiner can normally be reached on 8:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1641

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

LYL



Leon Y Lum
Patent Examiner
AU 1641
(571) 272-2878



CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP 1800 1641

8/19/04